Geosyntec consultants

14055 Riveredge Drive, Suite 3000
Tampa, Florida 33637
PH 813.558.0990
FAX 813.558.9726
www.geosyntec.com

21 January 2010

Ms. Demaree Collier
Work Assignment Manager (SR-6J)
Remedial Response Unit No. 1
U.S. Environmental Protection Agency Region 5
77 West Jackson Boulevard
Chicago, Illinois 60604

Subject: **Statistical Approach for Calculating Exposure Point Concentrations**
Human Health and Ecological Risk Assessments
Matthiessen and Hegeler Zinc Company Site
LaSalle, Illinois

Dear Ms. Collier:

Geosyntec Consultants (Geosyntec), on behalf of the Carus Corporation and Carus Chemical Company (Carus), and SulTRAC, on behalf of the U.S. Environmental Protection Agency (EPA), have reviewed the comments provided by the Illinois Environmental Protection Agency (IEPA) on the proposed statistical methodology for calculating exposure point concentrations (EPC) in the risk assessments for OU1 and OU2 of the Matthiessen and Hegeler Zinc Company Site. The initial statistical approach was described in an email transmitted to EPA 8 December 2009. The proposed approach for calculating EPCs can be summarized as follows:

- Use EPA's ProUCL, Version 4.00.04;
- Use ProUCL if at least 8 detected results are identified for a given data set; if not, then the maximum detected concentration will be used as the EPC; and
- Select the 95 percent upper confidence limit (UCL) of the statistical method recommended by ProUCL as the EPC. This approach is consistent with text from the Consensus Document, which states, "The EPC will be the 95 percent UCL of the statistical method recommended by ProUCL."

Ms. Connie Sullinger of IEPA provided the following comments (presented in normal font) on the proposed approach in an email dated 14 December 2009. This letter provides responses to these comments (presented in italic font), which were jointly prepared by the risk assessors and statisticians from Geosyntec and SulTRAC.

IEPA Comment 1: The consultants must remember that averaging of the exposure point concentration for the construction worker receptor is not allowed.

Response: SulTRAC and Geosyntec understand the need to evaluate some receptor pathways using this approach. EPCs for utility workers will also be point-based.

IEPA Comment 2: There still needs to be a cap on the percentage of nondetects. I know there is a note in the recommendations section of the ProUCL Version 4.00.04 Technical Guide that indicates that statistical estimates become unreliable at greater than a 70% censoring level. I am not comfortable leaving the statistical approach so simplistic.

Response: Under the current version of ProUCL (ver 4.00.04), there is no fixed percentage of detected values that are required to generate UCL statistics. Instead, ProUCL utilizes a minimum required sample size and, for some statistics, a minimum number of unique samples, to perform certain statistical procedures. The thought process behind adopting this approach was based on theoretical and empirical studies. Considerable research was conducted by EPA and others to develop an approach to handle censored data (Singh, A. and Nocerino, J.M. 2002. Robust Estimation of the Mean and Variance Using Environmental Data Sets with Below Detection Limit Observations, Chemometrics and Intelligent Laboratory Systems. 60:69-86; USEPA. 2006. Data Quality Assessment: Statistical Methods for Practitioners, EPA QA/G-9S. EPA/240/B-06/003. Office of Environmental Information, Washington, D.C. Download from: http://www.epa.gov/quality/qs-docs/g9s-final.pdf; Helsel, D.R., Hirsch, R.M. 1994. Statistical Methods in Water Resources. John Wiley; Kaplan, E.L. and Meier, O. 1958. Nonparametric Estimation from Incomplete Observations. Journal of the American Statistical Association, Vol. 53. 457-481.). This research was incorporated into the latest version of ProUCL. Statistical validation studies were performed by EPA on a range of censored datasets to confirm the ProUCL algorithms and support the use of ProUCL in environmental decision making (Singh, A. and Singh, A.K. 2007. ProUCL Version 4.0 Technical Guide. Publication EPA/600/R-07/041 – Appendix A. April 2007).

An alternative method of selecting the maximum value as an EPC for datasets with higher degrees of censoring is inconsistent with EPA's ProUCL guidance, which specifically states:

> *"**Note**: It is recommended that the maximum observed value NOT be used as an estimate of the EPC term representing average exposure contracted by an individual over an [Exposure Area] EA." (ProUCL User Guide)*

While it is acknowledged that high degrees of censoring and low number of unique samples may result in additional uncertainty, the guidance suggests that the maximum is associated with a greater degree of uncertainty and should be avoided. Rather, the ProUCL guidance suggests the following when confronted with a high degree of censoring and low number of detected values:

> ***"Note:*** *In case the number of available detected samples is small (< 5), it is suggested that the project team decide about the estimation of the EPC term on site-specific basis. For such small data sets with very few detected values (< 5), the final decision ("policy decision") on how to estimate the EPC term should be determined by the project team and decision makers." (ProUCL User Guide)*

Based on these considerations, we recommend using the ProUCL 4.00.04 software as a primary guide to the selection of the appropriate EPC for site datasets, including datasets with higher degrees of censoring. However, as a more conservative assumption, ProUCL statistics will only be developed for datasets with 8 or more detected values. Available research and guidance suggest that meaningful UCL statistics can be generated with this level of data regardless of the percentage of censoring in the dataset. All statistical calculations and EPC recommendations will be reviewed by our statistical team to ensure that alternative techniques to deal with highly unusual datasets are not warranted. Should an alternative evaluation be deemed necessary, we will provide the appropriate justification.

The Geosyntec and SulTRAC statisticians have worked with both Anita Singh (lead author of the ProUCL software) and Dennis Helsel (former USGS employee who has devoted much of his career to properly interpreting censored data) in the past. Should IEPA feel that this response misinterprets the work presented by these practitioners, we would be more than willing to assist EPA in finding a mechanism to engage them for input.

If you have any questions, please do not hesitate to call me at 813-558-0990.

Sincerely,

J. Keith Tolson, Ph.D.
Director of Toxicology

cc: Andrew Podowski, EPA
Connie Sullinger, IEPA
Ray Bienert, SulTRAC
David Homer, SulTRAC
Jennifer Knoepfle, SulTRAC
Eric Morton, SulTRAC
Rich Berggreen, Geosyntec
Terry Cheek, Geosyntec
Nandra Weeks, Geosyntec